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PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Madison et al.	)	
	)	
Serial No. : 09/091,578	)	Group Art Unit: 1644
	)	
Filed: June 19, 1998	)	Examiner: Dibrino, M.
	)	
For: TARGETED THERAPEUTIC OR DIAGNOSTIC AGENTS AND METHODS OF MAKING AND USING SAME	)	

ELECTION UNDER RESTRICTION REQUIREMENT

VIA FACSIMILE TRANSMISSION
703/305-3704
ATTN: Examiner M. DiBrino
Assistant Commissioner for Patents
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

August 30, 1999

Sir:

This is in response to the Office Action dated June 30, 1999, wherein restriction of the claims of the above-identified application is required. A Request for Extension of Time is included herewith. The Office Action requires restriction to one of the following twelve groups of claims:

Group I: Claims 1-24, drawn to a therapeutic/diagnostic agent.

Group II: Claims 25-37, drawn to a recombinant targeting protein and a pharmaceutical composition thereof.

Group III: Claims 38-45, drawn to a nucleic acid encoding a recombinant targeting protein and nucleic acid that hybridizes to said nucleic acid.

Group IV: Claims 46, 47 and 48, drawn to a method of reducing a blood clot/

preventing thrombosis/treating myocardial infarction in a subject using the protein of claim 33.

Group V: Claim 49, drawn to a method of targeting a therapeutic compound to a tumor using the agent of claim 24.

Group VI: Claim 50, drawn to a method of targeting a compound to a tumor using the protein of claim 31.

Group VII: Claim 51, drawn to a method of targeting a therapeutic protein to an osteoclast using the agent of claim 24.

Group VIII: Claim 52, drawn to a method of targeting a therapeutic protein to an osteoclast using the agent of claim 31.

Group IX: Claim 53, drawn to a method of targeting a therapeutic compound to an endothelial cell using the agent of claim 24.

Group X: Claim 54, drawn to a method of targeting a therapeutic compound to a tumor/tumor cell expressing $\alpha V\beta I$ integrin using the agent of claim 24.

Group XI: Claim 55, drawn to a method of targeting a therapeutic compound to a vascular smooth muscle cell using the agent of claim 24.

Group X: Claims 56-64, drawn to a method of designing a targeted protein.

The Office Action further states that a single disclosed species must also be elected to which claims would be restricted if no generic claim is finally held to be allowable and to list all claims readable thereon. With respect to the species election requirement, the Office Action additionally states that applicants are required to elect a specific agent comprising a specific therapeutic or diagnostic functional entity linked to a specific peptide mimetic or a specific protein or a specific polyamino acid which binds specific target.

Applicants respectfully request that the entire restriction requirement be reconsidered because the present application is a national phase application under 37 C.F.R. § 371 and no unity of invention issue was raised during prosecution of original claims 1-55 in the PCT application by either the International Search Authority or the International Preliminary

Examination Authority, both of which were the U.S. PTO. Furthermore, both the Written Opinion and the International Preliminary Examination Report of the PCT application state that claims 1-55 have novelty, which is contrary to the Examiner's position that the invention of Group I has no special technical feature that defined the contribution over the prior art. Therefore, claims 1-55 have previously been determined by the U.S. PTO to relate to a single general inventive concept and to possess a technical feature which defines a contribution over the prior art and thus fulfill the requirement of unity of invention as set forth in PCT Rule 13. Furthermore, new claims 56-64 recite methods of making targeted proteins having features of the compositions of the original claims and are, thus, also related to the same general inventive concept attributed to claims 1-55. For these reasons, applicants respectfully request that the restriction be withdrawn and that all of the pending claims be examined together as a whole.

As required in response to this Action, applicants provisionally elect Group I (claims 1-24), with traverse. Applicants further provisionally elect a *thrombolytic agent/anticoagulant* as a therapeutic or diagnostic functional entity, a *complementarity determining region (CDR) of an immunoglobulin* as a specific peptide mimetic source or a specific protein or a specific polyamino acid and *integrin* as a specific target. Claims 1-8, 10-17, 19-21, 23-24 are readable on the elected species and claims 9 (which recites thrombolytic agent or an anticoagulant), 18 (which recites integrin), and 22 (which recites a complementarity determining region of an IgG-like molecule) are partially readable on the elected species. Applicants acknowledge that, upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species.

Furthermore, on the basis that a determination of unity of invention under PCT Rule 13 permits the inclusion of certain combinations of claims of different categories [see M.P.E.P. § 1850, Subsection C ("Combinations of Different Categories of Claims") under the heading: "The Requirement for 'Unity of Invention'", which states the following: "...(A) In addition to an independent claim for a given product, ...an independent claim for a use of the said product...."]. applicants request that if the present grouping of claims still stands in view of applicants' above

comments that the claims of Groups V, VII, IX, X and XI be examined together with the claims of Group I, because all of the claims of groups V, VII, IX, X and XI recite the use of the agent of claim 24, which is included in Group I, which applicants have provisionally elected herein with traverse.

Applicants also wish to remind the Examiner of the guidelines for rejoinder of claims as set forth in M.P.E.P. § 821.04, as they apply to the pending claims of the instant application.

A Request for Extension of Time is filed herewith and the Commissioner is authorized to charge the $55.00 Extension of Time fee and any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted

Mary L. Miller
Registration No. 39,303

Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811
(404) 688-0770

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being sent via facsimile transmission to 703/305-3704, ATTN: Examiner M. Dibrino, Assistant Commissioner for Patents, Washington, D.C. on the date shown below.

Mary L. Miller — August 30, 1999
Date